K080495
Page 1 of 2

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Mary Kruitwagen
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

Tel: 978-659-4932
Fax: 978-685-5624
Email: mary.kruitwagen@philips.com

MAR 24 2008

This summary was prepared on February 15, 2008.

2. The names of the subject devices are the Philips SureSigns VM Series Patient Monitors and SureSigns VS3 Vital Signs Monitor.

3. The trade names of the devices are the SureSigns VM Series Patient Monitors (VM3, VM4, VM6, VM8) and the SureSigns VS3 Vital Signs Monitor.

4. The common usual name is multi-parameter patient monitor

5. The Classification names are as follows:

Device Panel	Classification	ProCode	Description
Circulatory System Devices	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	870.1110, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive
	870.1435, II	DXG	Computer, Diagnostic, Pre-programmed, Single-function
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm
	870.2340, II	DPS	Electrocardiograph
	870.2700, II	DQA	Oximeter
	870.2850, II	DRS	Extravascular Blood Pressure Transducer
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas,
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical

6. The modified devices are substantially equivalent to previously cleared Philips device, M3046B Compact Configurable Portable Patient Monitor marketed pursuant to K052707.

7. The modifications are changes to the SureSigns VM Series Patient Monitors and the SureSigns VS3 Vital Signs Monitor. These changes include two new models, enhancements and bug fixes. The new models include the VM3 Series Patient Monitor which is a subset of the predicate devices but does not perform NBP and the SureSigns VS3 Vital Signs monitor which is a subset of the predicate device and performs continuous SpO2 and intermittent measurements of SpO2, NBP, and pTemp. The enhancements include improvements in the areas of Patient Records, the Administering Patients, Networking, Data Export, improved board hardware, adding a SpO2 sensor and NBP cuffs.

8. The modified devices have the same intended use as the legally marketed predicate device. The SureSigns VS3 vital signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. For monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitors may be used in transport situations within a healthcare facility.

9. The modified devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same design as the predict device. The composition of the materials used for both devices is the same. There is no change to the chemical composition of the subject devices to the predicate devices. The energy source of the subject devices is essentially the same as the predicate device.

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VM Series Patient Monitors and SureSigns VS3 Vital Signs Monitor meet all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2008

Philips Medical Systems
c/o Ms. Mary Kruitwagen
Regulatory Affairs Specialist
3000 Minuteman Rd.
Andover, MA 01810

Re: K080495
Trade/Device Name: Philips SureSigns VM series Patient Monitors and SureSigns VS3 Vital Sign Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: February 15, 2008
Received: February 22, 2008

Dear Ms. Kruitwagen:

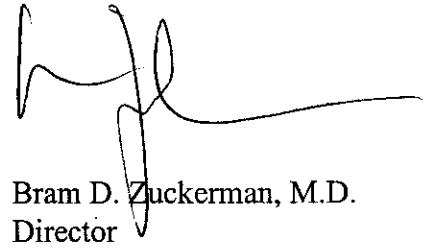
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K080495

Device Name: Philips SureSigns VM Series Patient Monitors and SureSigns VS3 Vital Signs Monitor

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Intended Use: For monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitor is intended for use in transport situations within a healthcare facility.

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080495